MEDERR DDP REPORT

Access Number: 040892
28-Oct-02 02:51:59 PM **erf**

Date Received at USP: 16-May-9 **Date of Report**

Product Name:	VENTOLIN NEBULES	**Container Type:**	UNIT-DOSE
Generic Name(s):	ALBUTEROL SULFATE	**Container Size:**	3 ML
Manufacturer:	ALLEN & HANBURYS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	Yes

Product Name:	ATROVENT	**Container Type:**	UNIT-DOSE
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	2.5 ML
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	Yes

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error?

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error?

When and how was the error discovered?

Where did the error occur?

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 040892

28-Oct-02 02:52:00 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

POTENTIAL ERROR: ALTHOUGH THE BOXES THAT THE UNIT-DOSE VIALS ARE PACKAGED IN ARE VERY DIFFERENT, THE UNIT-DOSE VIALS THEMSELVES LOOK IDENTICAL EXCEPT FOR THE SHAPE OF THE SNAP OFF TOP. IT IS FEARED THAT PRACTITIONERS, ESPECIALLY RESPIRATORY THERAPISTS WILL CONFUSE THE TWO WHEN THEY ARE TAKEN OUT OF THE BOX TO BE USED FOR PATIENTS. THE REPORTER RECOMMENDS THAT THE CLEAR PLASTIC UNIT-DOSE VIALS SHOULD HAVE PAPER LABELS ON THEM, SO THAT ONE CAN READ THE NAME OF THE DRUG.

MEDERR DDP REPORT

Access Number: 040914
28-Oct-02 02:52:00 PM **erf**

Date Received at USP: 09-Jun-94 **Date of Report**

Product Name:	ATROVENT	**Container Type:**	UNIT-DOSE
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.5 MG/2.5 ML	**Sample Available:**	No

Product Name:	VENTOLIN	**Container Type:**	UNIT-DOSE
Generic Name(s):	ALBUTEROL SULFATE	**Container Size:**	
Manufacturer:	ALLEN & HANBURYS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	2.5 MG/3 ML	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error?

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error?

When and how was the error discovered?

Where did the error occur?

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 040914

28-Oct-02 02:52:00 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

POTENTIAL ERROR: THE PACKAGING OF ATROVENT INHALATION SOLUTION AND VENTOLIN NEBULES IS VERY SIMILAR. THE POTENTIAL PROBLEM IS THAT SINCE BOTH AGENTS ARE USED IN JUST NEBULIZER TREATMENTS, THEY COULD EASILY BE CONFUSED. THE WRITING ON THE PLASTIC CONTAINER IS IN CLEAR WRITING AND DIFFICULT TO READ; THEREFORE IF THE PACKAGING IS SIMILAR AND THE WRITING DIFFICULT TO READ, THE TWO CAN BE EASILY CONFUSED. THE REPORTER RECOMMENDS EITHER ADD A DIFFERENT COLOR TO THE WRITING ON THE PLASTIC CONTAINER OR ADD COLOR TO THE TAB ON THE END OF EACH CONTAINER.

MEDERR DDP REPORT

Access Number: 041020

28-Oct-02 02:52:00 PM **erf**

Date Received at USP: 19-Aug-9 **Date of Report**

Product Name:	ATROVENT	**Container Type:**	AMPUL
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	ALBUTEROL SULFATE	**Container Type:**	AMPUL
Generic Name(s):	ALBUTEROL SULFATE	**Container Size:**	
Manufacturer:	VARIOUS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error?

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error?

When and how was the error discovered?

Where did the error occur?

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 041020

28-Oct-02 02:52:00 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

BOTH AMPULS LOOK VERY SIMILAR. THIS COULD CAUSE AN ERROR. THE PERSONNEL IN THE RESPIRATORY THERAPY DEPARTMENT ASKED THE PHARMACY TO PACKAGE THEM DIFFERENTLY TO AVOID CONFUSION. THIS INCIDENT HAS BEEN REPORTED TO THE INSTITUTION. THE REPORTER RECOMMENDS BOTH MANUFACTURERS SHOULD BE NOTIFIED THAT THE LABELING, SIZING OR COLORING OF BOTH DRUGS NEED TO BE CHANGED TO DIFFERENTIATE BETWEEN THE TWO.

MEDERR DDP REPORT

Access Number: 041119
28-Oct-02 02:52:00 PM **erf**

Date Received at USP: 02-Nov-9 **Date of Report**

Product Name:	ATROVENT	**Container Type:**	
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.5 MG/2.5 ML	**Sample Available:**	No

Product Name:	VENTOLIN	**Container Type:**	
Generic Name(s):	ALBUTEROL SULFATE	**Container Size:**	
Manufacturer:	ALLEN & HANBURYS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	2.5 MG/3 ML	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome: N/A

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Pharmacist

When and how was the error discovered? N/A

Where did the error occur? Hospital pharmacy

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:
N/A

MEDERR DDP REPORT

Access Number: 041119

28-Oct-02 02:52:00 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

POTENTIAL ERROR ONLY. IPRATROPIUM BROMIDE AND ALBUTEROL SULFATE LOOK IDENTICAL AND CAN BE EASILY INTERCHANGED.

MEDERR DDP REPORT

Access Number: 041258
28-Oct-02 02:52:00 PM **erf**

Date Received at USP: 02-Feb-95 **Date of Report**

Product Name:	VENTOLIN NEBULES	**Container Type:**	
Generic Name(s):	ALBUTEROL SULFATE	**Container Size:**	
Manufacturer:	ALLEN & HANBURYS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	ATROVENT	**Container Type:**	
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.5 MG/2.5 ML	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome: NA

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered? NA

Where did the error occur? HOSPITAL PHARMACY

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:
NA

MEDERR DDP REPORT

Access Number: 041258

28-Oct-02 02:52:00 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

THE REPORTER IS WRITING IN ORDER TO EXPRESS HIS CONCERNS OVER POSSIBLE MEDICATION ERRORS OCCURRING FROM THE UNINTENDED DISPENSING OF VENTOLIN NEBULE (3 ML FOR INHALATION) FOR ATROVENT (0.5 MG/2.5 ML FOR INHALATION). THE REPORTER IS AWARE THAT THE PRODUCT HAS A V FOR VENTOLIN AT THE TOP FOR EASE OF OPENING, HOWEVER, BECAUSE OF THE SIMILARITY (ALMOST IDENTICAL) COLOR, SIZE, SHAPE AND RAISED LETTERING, THE REPORTER IS SURE THAT IT IS JUST A MATTER OF TIME BEFORE SERIOUS MEDICATION ERRORS OCCUR WITH THE PRODUCT. THEREFORE, THE REPORTER IS REQUESTING THE FIRMS TAKE A SERIOUS LOOK AT THE PACKAGING FOR THIS PRODUCT WITH THE INTENTION OF CHANGING SOMETHING SO AS TO ALLOW EASIER IDENTIFICATION.

MEDERR DDP REPORT

Access Number: 041294

28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 17-Feb-95 **Date of Report**

Product Name:	ATROVENT	**Container Type:**	UNIT-DOSE
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.5 MG/2.5 ML	**Sample Available:**	No

Product Name:	SODIUM CHLORIDE	**Container Type:**	UNIT-DOSE
Generic Name(s):	SODIUM CHLORIDE	**Container Size:**	
Manufacturer:	VARIOUS	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome: NA

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered? NA

Where did the error occur? HOSPITAL PHARMACY

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:
NA

MEDERR DDP REPORT

Access Number: 041294

28-Oct-02 02:52:01 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

A POTENTIAL EXISTS THAT ATROVENT, WHICH IS IN A CLEAR CONTAINER SIMILAR TO THE CONTAINERS OF MANY BRANDS OF SODIUM CHLORIDE, COULD BE MISTAKEN FOR SODIUM CHLORIDE. NO ERROR OCCURRED. THE REPORTER RECOMMENDS THAT THE ATROVENT LABELING SHOULD HAVE SOME COLOR ADDED.

MEDERR DDP REPORT

Access Number: 041578
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 24-Aug-9 **Date of Report**

Product Name:	ATROVENT	**Container Type:**	
Generic Name(s):	IPRATROPIUM BROMIDE	**Container Size:**	
Manufacturer:	BOEHRINGER ING	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.5 MG/ML	**Sample Available:**	No

Product Name:	SODIUM CHLORIDE	**Container Type:**	
Generic Name(s):	SODIUM CHLORIDE	**Container Size:**	
Manufacturer:	WYETH AYERST	**NDC Number:**	
Labeler:		**Adm. Route:**	INHALATION
Dosage Form:	SOLUTION	**Lot Number(s):**	
Strength:	0.9%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 041578

28-Oct-02 02:52:01 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

THE UNIT-DOSE CONTAINERS OF ATROVENT AND SODIUM CHLORIDE LOOK VERY SIMILAR CREATING A POTENTIAL FOR ERROR. [redacted] THIS CAN BE A DANGEROUS MIX-UP IF A PATIENT WITH SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE MISSES DOSES OF HIS OR HER ORDERED ATROVENT BECAUSE A NURSE HURRIEDLY GRABS SODIUM CHLORIDE. OR, IF A PATIENT REQUIRING ONLY A SALINE NEBULIZER TREATMENT IN ORDER TO HELP HIM OR HER EXPECTORATE A SPUTUM SAMPLE IS GIVEN ATROVENT BY MISTAKE, THAT PATIENT MAY SUFFER SIDE EFFECTS SUCH AS NERVOUSNESS, DIZZINESS, HEADACHE, NAUSEA, OR HEART PALPITATIONS. IF FACILITIES STOCK SIMILAR LOOKING UNIT-DOSE SOLUTIONS OF NEBULIZER MEDICATIONS, CONSIDER CONTAINERS IN DIFFERENT COLORS. THE MEDICATION WAS NOT ADMINISTERED TO OR USED BY THE PATIENT. THE REPORTER RECOMMENDS TO CHANGE THE PACKAGING, ORDER DIFFERENT BRANDS, STORE THE TWO MEDICATIONS IN DIFFERENT AREAS, AND READ THE LABEL CAREFULLY BEFORE ADMINISTRATION.

MEDERR DDP REPORT

Access Number: 042242
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 06-Jan-97 **Date of Report** 02-Jan-97

Product Name:	Gastrocrom	**Container Type:**	Plastic ampul
Generic Name(s):	Cromolyn Sodium	**Container Size:**	
Manufacturer:	Medeva Pharmaceuticals	**NDC Number:**	53014-0678-70
Labeler:		**Adm. Route:**	Oral
Dosage Form:	Concentrate	**Lot Number(s):**	
Strength:	100 mg/5 mL	**Sample Available:**	No

Product Name:	Cromolyn Sodium	**Container Type:**	Plastic ampul
Generic Name(s):	Cromolyn Sodium	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	10 mg/mL	**Sample Available:**	No

Product Name:	Intal	**Container Type:**	Plastic ampul
Generic Name(s):	Cromolyn Sodium	**Container Size:**	
Manufacturer:	Fisons	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	10 mg/mL	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 042242

28-Oct-02 02:52:01 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Change the packaging of Gastrocrom, perhaps by utilizing a screw-on top, so that it looks more like oral packaging.

REMARKS

Problem:

A reporter received information on a new product named Gastrocrom 100 mg/5 mL, an oral concentrate, packaged in a plastic ampul. He noticed that the ampul is exactly the same size and shape as the plastic ampuls of Intal and Cromolyn Sodium for inhalation. The reporter feels that someone using the oral concentrate and also frequently using the inhalation solution, could accidentally or deliberately use the oral concentrate in an inhalation machine and receive a five-fold overdose.

Dey Laboratories letter to USP dated 2/28/97: The Dey Laboratories vial is a completely different shape and size from the other two product vials. Dey Laboratories' Cromolyn Sodium Inhalation Solution USP is labeled with a yellow and blue paper label on each vial. This vial contains the product name and strength information.
Medeva Pharmaceuticals letter to USP dated 4/15/97: Gastrocrom Oral Concentrate ampuls are significantly larger than the other ampuls in question. Gastrocrom ampuls measure approximately 4" x 1/2" and contain five (5) mLs of product while the other ampuls are approximately 2 1/4" x 1/2" and contain only two (2) mLs of product. Additionally, the Gastrocrom ampuls are clearly labeled as being an oral concentrate and for oral use only.

MEDERR DDP REPORT

Access Number: 050615
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 17-Nov-9 **Date of Report** 13-Nov-9

Product Name:	Pulmozyme	**Container Type:**	Ampul
Generic Name(s):	Dornase Alfa	**Container Size:**	2.5 mL
Manufacturer:	Genentech	**NDC Number:**	50242-100-37
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1 mg/mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The labeling on Pulmozyme is confusing and dangerous.

MEDERR DDP REPORT

Access Number: 051073
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 01-Apr-98 **Date of Report** 31-Mar-9

Product Name: Ipratropium Bromide	**Container Type:** 2.5 mL
Generic Name(s): Ipratropium Bromide	**Container Size:**
Manufacturer: Roxane	**NDC Number:** 0054-8402-11
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.02%	**Sample Available:** No

Product Name: Sodium Chloride Inhalation Solution	**Container Type:**
Generic Name(s): Sodium Chloride Inhalation Solution	**Container Size:**
Manufacturer: Unknown	**NDC Number:**
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength:	**Sample Available:** No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 051073

28-Oct-02 02:52:01 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Labeling of the Ipratropium Bromide vials could lead to medication errors. The clear plastic vials are labeled with raised lettering; no paper label is attached. This makes reading the contents extremely difficult. The vials also resemble several brands of Saline inhalation vials, which could lead to potential errors.

Roxane Laboratories, Inc. letter sent to reporter dated March 27, 1998: Suggestion that we replace the embossing with a printed label will be forwarded to our Product Management Committee for review.

MEDERR DDP REPORT

Access Number: 052296
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 27-Apr-99 **Date of Report** 27-Apr-99

Product Name:	Naropin	**Container Type:**	Polyamp Duofit
Generic Name(s):	Ropivacaine Hydrochloride	**Container Size:**	Various
Manufacturer:	Astra	**NDC Number:**	
Labeler:		**Adm. Route:**	Injection
Dosage Form:	Injectable	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Xylocaine-MPF	**Container Type:**	Polyamp Duofit
Generic Name(s):	Lidocaine Hydrochloride	**Container Size:**	Various
Manufacturer:	Astra	**NDC Number:**	
Labeler:		**Adm. Route:**	Injection
Dosage Form:	Injectable	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/2.5 mL	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 052296

28-Oct-02 02:52:01 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Change the packaging, label well, and distribute notices of the potential for error.

REMARKS

Problem:

The Polyamp Duofit packaging of Naropin (Ropivacaine Hydrochloride) and Xylocaine MPF (Lidocaine Hydrochloride) is very similar to that of Ipratropium Bromide inhalation solution and could potentially be confused.

Dey letter sent to USP dated May 25, 1999. Although there are other distinct differences between Dey's packaging of the injectable products, the vial size is the most obvious and evident difference which would prevent Dey's Ispratropium Bromide from being mistaken for one of the injectable products mentioned. Of course, it is always vitally important for the health care provider and pharmacist to carefully inspect the labeling of a medication before administration in order to prevent errors; however, given the great size difference, Dey does not believe there is any potential for confusion or error involving Dey's Ipratropium Bromide and Naropin and Xylocaine MPF.

MEDERR DDP REPORT

Access Number: 052830
28-Oct-02 02:52:01 PM **erf**

Date Received at USP: 27-Jan-00 **Date of Report** 27-Jan-00

Product Name:	Ipratropium Bromide	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Product Name:	Cromolyn Sodium	**Container Type:**	
Generic Name(s):	Cromolyn Sodium	**Container Size:**	2 mL
Manufacturer:	Arcola Labs	**NDC Number:**	00070-9996-06
Labeler:	Automatic Liquid Packaging	**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	20 mg/2 mL	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:	Automatic Liquid Packaging	**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 052830

28-Oct-02 02:52:02 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

A respiratory therapist brought this concern to the attention of the pharmacy. The inhalation solutions, Ipratropium Bromide, Cromolyn Sodium, and Xopenex unit-dose vials look almost identical to each other and the labels on the vials are difficult to read.

Roxane Laboratories letter to the reporter dated 2/25/00: Comments about the embossing on the vial will be forwarded to the Product Management Committee for review.
Sepracor letter to the reporter dated 4/24/00: In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this, require FDA approval before marketed to consumers and therefore require additional time to implement.
Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 052894
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 22-Feb-00 **Date of Report** 22-Feb-00

Product Name:	Atrovent	**Container Type:**	Unit-dose ampuls
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Boehringer Ingelheim	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Unit-dose ampuls
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 052894

28-Oct-02 02:52:02 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

It is possible to mix-up Atrovent and Xopenex ampuls. Both products are clear plastic ampules.

Sepracor letter to USP dated 4/24/00: In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this, require FDA approval before marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 052946

28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 20-Mar-0 **Date of Report** 20-Mar-0

Product Name:	Gastrocrom	**Container Type:**	
Generic Name(s):	Cromolyn Sodium	**Container Size:**	5 mL
Manufacturer:	Medeva Pharmaceuticals	**NDC Number:**	
Labeler:		**Adm. Route:**	Oral
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? Pharmacist

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/I

When and how was the error discovered?

Where did the error occur? N/I

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 052946

28-Oct-02 02:52:02 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Gastrocrom and Xopenex have similar packaging and can be easily mixed up. The error was noted when someone was putting away returned medications. The patient did not receive the incorrect drug.

Medeva Pharmaceuticals, Inc. letter to USP dated 5/10/00: A review of complaint files did not reveal any other complaints of this type for Gastrocrom Oral Concentrate. As such, this is considered to be an isolated incident.

MEDERR DDP REPORT

Access Number: 053003
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 06-Apr-00 **Date of Report** 06-Apr-00

Product Name:	Ipratropium Bromide	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:
Need an actual label instead of an imprint.

REMARKS

Problem:
The labeling on Ipratropium Bromide is an imprint, which is difficult to read. This could lead to an error.

Roxane Laboratories letter to the reporter dated 5/5/00: The suggestion that the company enhance the embossing or replace the product with a printed label will be forwarded to the Product Management Committee for review.

MEDERR DDP REPORT

Access Number: 053280
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 28-Aug-0 **Date of Report** 28-Aug-0

Product Name:	Cromolyn Sodium	**Container Type:**	unit-dose vial
Generic Name(s):	Cromolyn Sodium	**Container Size:**	2 mL
Manufacturer:	Dey	**NDC Number:**	49502-0689-02
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	20 mg/2 mL	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	unit-dose vial
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Pharmacist

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Pharmacist

When and how was the error discovered? The pharmacist realized the error later on in the day.

Where did the error occur? Outpatient pharmacy

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? Yes

If yes, before or after error was discovered? Both

Number of occurrences:

Patient information that might be relevant:
The patient is a 5-year-old male.

MEDERR DDP REPORT

Access Number: 053280

28-Oct-02 02:52:02 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Redundant check of product and label by the pharmacist and technician prior to dispensing medications to patients.

REMARKS

Problem:

A healthcare provider entered a prescription for generic Intal (Cromolyn Sodium) nebulization solution, but filled the prescription with generic Atrovent (Ipratropium Bromide) nebulization solution and dispensed it to the patient. The filling pharmacist realized the error later in the day and called the patient at home. The prescription was returned for correction.

MEDERR DDP REPORT

Access Number: 053436
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 24-Oct-00 **Date of Report** 24-Oct-00

Product Name:	Albuterol Sulfate	**Container Type:**	unit-dose
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Steripak Limited	**NDC Number:**	00172-6405-44
Labeler:	Zenith Goldline	**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No

Product Name:	HypoTears PF	**Container Type:**	unit-dose
Generic Name(s):	Polyvinyl Alcohol PEG 400 Dextrose	**Container Size:**	0.45 mL
Manufacturer:	Ciba	**NDC Number:**	58768-0132-30
Labeler:		**Adm. Route:**	Ophthalmic
Dosage Form:	Drops	**Lot Number(s):**	
Strength:	1%	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Nurse, registered

Describe Outcome: The medication was not administered.

If the medication did not reach the patient, describe the intervention. The floor registered nurse brought the appearance of the two unit-dose drugs to the attention of the superiors. Nursing then brought this to the reporter's attention.

Who discovered the error? Nurse, registered

When and how was the error discovered? The registered nurse recognized the Albuterol and questioned why it should be in the medication drawer since that would be in violation of the policy. The nurse also observed that this patient was using Hypo Tears PF.

Where did the error occur? Nursing home

Was another practitioner involved in the error? Yes

If yes, what type of practitioner? Respiratory therapist or LPN

Was patient counseling provided? No

MEDERR DDP REPORT

Access Number: 053436

28-Oct-02 02:52:02 PM **erf**

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

The patient is a female in her 70's with dry eyes.

Reporter's recommendations or policies to prevent future similar errors:

Have the manufacturer improve the labeling of both products so that the label can be clearly read and the containers distinguished. The Albuterol for inhalation now being used is manufactured by Dey and contains a nice blue adhesive label that is easy to read.

REMARKS

Problem:

A registered nurse was passing medications on the general floor of a nursing home. The nurse opened the medication drawer and found a plastic unit-dose vial of Albuterol for inhalation. The patient is not on Albuterol for Inhalation, but is using Hypo Tears PF. The registered nurse noticed that the containers of both products are very difficult to read and similar in appearance (size, shape, color, imprinting style). Both products have clear plastic with identifying information molded into the container itself. The products could be easily misidentified by a busy nurse on a short-staffed unit and the inhalation product instilled into the eye. The registered nurse caught the error by recognizing the Albuterol container and realizing that this product should not be in the patient's medication drawer by the policy.

Zenith Goldline Pharmaceuticals letter to USP dated 11/16/00: This will acknowledge receipt of the correspondence, the file number 053436.

MEDERR DDP REPORT

Access Number: 053529
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 05-Dec-00 **Date of Report** 05-Dec-00

Product Name:	Pulmicort	**Container Type:**	Plastic respules
Generic Name(s):	Budesonide	**Container Size:**	
Manufacturer:	Astra	**NDC Number:**	00186-1988-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.25 mg/2 mL	**Sample Available:**	No

Product Name:	Pulmicort	**Container Type:**	Plastic respule
Generic Name(s):	Budesonide	**Container Size:**	
Manufacturer:	Astra	**NDC Number:**	00186-1989-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.5 mg/2 mL	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? Technician, pharmacy

Describe Outcome:

If the medication did not reach the patient, describe the intervention. Respiratory therapist caught the mistake and the error was avoided.

Who discovered the error? Respiratory therapist

When and how was the error discovered? The error was discovered when the respiratory therapist went to the drawer to administer respiratory treatment requiring budesonide respules.

Where did the error occur? Hospital

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053529

28-Oct-02 02:52:02 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

If the company can't mark the plastic respule with a color or identifying mark, then the different strengths should be separated when shipped, placed in well-marked bins, and have some sort of identifying sticker placed on them when dispensed. Care should be taken when crediting and returning the respule to the storage bin. The storage bins are now marked more clearly and e-mail has been sent out warning pharmacy technicians and pharmacists about the potential for error.

REMARKS

Problem:

Pulmicort respules 0.25 mg/2 mL and 0.5 mg/2 mL are very similar in packaging size and were mixed up in the pharmacy storage bins. The incorrect strength was placed in the patient's medication drawers. The respiratory therapist caught the mistake and the error was avoided.

MEDERR DDP REPORT

Access Number: 053698
28-Oct-02 02:52:02 PM **erf**

Date Received at USP: 06-Feb-01 **Date of Report** 06-Feb-01

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Zenith	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Roxane	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053698

28-Oct-02 02:52:03 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Modify packaging; give each distinguishing characteristics.

REMARKS

Problem:

This problem was brought to the attention of the reporter by the Respiratory Department. The following inhalation products are packaged similarly and could contribute to a medication error: Albuterol Sulfate inhalation solution by Zenith and Ipratropium Bromide inhalation solution by Roxane. The two products are in ready to use vials and the boxes are different, but since most respiratory technicians break open the foil packs and carry the vials, there needs to be some distinguishing features to the individual packaging (colored plastic in the vial or a label on the outside of the vial similar to Dey's Albuterol inhalation soultion).

MEDERR DDP REPORT

Access Number: 053735

28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 14-Feb-01 **Date of Report** 14-Feb-01

Product Name:	Ipratropium Bromide	**Container Type:**	Ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Roxane's Ipratropium Bromide Inhalation solution 0.02% unit-dose vials 2.5 mL has poor labeling. This medication almost caused a medication error in the emergency room. Once the outer foil packaging is removed it is very difficult to read the clear, raised letters on each unit. The hospital will try to order another brand that has each unit more clearly marked.

MEDERR DDP REPORT

Access Number: 053736

28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 14-Feb-01 **Date of Report** 14-Feb-01

Product Name:	Ipratropium Bromide	**Container Type:**	Vial
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Roxane	**NDC Number:**	00054-8402-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Vial
Generic Name(s):	Levalbuterol Hydrchloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053736

28-Oct-02 02:52:03 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The reporter wrote to suggest the labeling of respiratory inhalation treatment vials be considered as an issue by ISMP (Institute of Safe Medication Practices). Specifically, labeling of respiratory medication pre-mix vials by imprinting the labeling information during the molding process for the vial. Many people find this very difficult to read. Many inhalation solutions come in pre-mixed vials, which are labeled only by the imprinting of product information on the exterior of the vial. [redacted] The addition of a paper label or a color identifier would greatly aid in the discrimination of one vial from another.

MEDERR DDP REPORT

Access Number: 053793
28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 05-Mar-0 **Date of Report** 05-Mar-0

Product Name:	Xopenex	**Container Type:**	vial
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:
Encourage manufacturers to change its labeling habits.

REMARKS

Problem:
Fortunately, this has not been either a potential or actual occurrence. However, the reporter has received a number of phone messages from respiratory therapists and pulmonologists on staff regarding the labeling of the Xopenex (Levalbuterol) jets. Any efforts to encourage the manufacturer to change its labeling habits would be most appreciated.

Information per call to reporter: The product is packaged in a clear plastic container. There is no label on the container; the product information is imprinted on the plastic, which is difficult to read.

MEDERR DDP REPORT

Access Number: 053793

28-Oct-02 02:52:03 PM **erf**

Sepracor letter to the reporter dated 7/12/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible and would further differentiate the Xopenex Inhalation Solution products.

MEDERR DDP REPORT

Access Number: 053811
28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 13-Mar-0 **Date of Report** 13-Mar-0

Product Name:	Xopenex	**Container Type:**	Unit-dose vial
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Unit-dose vial
Generic Name(s):	Levalbuterol Hydrchloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053811

28-Oct-02 02:52:03 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

The reporter feels that the manufacturer should create vials of different strengths that are more readily seen as different.

REMARKS

Problem:

A potential error caused by the packaging of the drug Xopenex (Levalbuterol manufactured by Sepracor) in the 1.25 mg and 0.63 mg unit-dose vials. While the outer wrappers (box and inner foil wrapper) of the two strengths differ in appearance, the vials themselves are distinguishable only upon very careful examination of the labels. The reporter feels that the manufacturer should create vials of different strengths that are more readily seen as different. Any help that would end this confusion would be appreciated.

Sepracor letter to the reporter dated 7/12/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible and would further differentiate the Xopenex Inhalation Solution products.

MEDERR DDP REPORT

Access Number: 053887
28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 29-Mar-0 **Date of Report** 29-Mar-0

Product Name:	Xopenex	**Container Type:**	unit-dose vial
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	unit-dose vial
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Respiratory therapist

Describe Outcome:

If the medication did not reach the patient, describe the intervention. The physician inspected the unit-dose package, determined that it was not the right dose and prevented the error.

Who discovered the error? Physician

When and how was the error discovered?

Where did the error occur? Hospital

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053887

28-Oct-02 02:52:03 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

The medications require different packaging or labeling. Printing the name and strength of the medication in color would be most useful. A consideration to prevent potential errors in the future is to remove the medication from the hospital formulary because safe and effective alternatives exist.

REMARKS

Problem:

Prior to administration of a dose of Xopenex, a physician noticed that the respiratory therapist had mistakenly opened the wrong strength of medication. By inspecting the unit-dose package, the physician prevented the error. The error almost occurred because the two product strengths are virtually identical in appearance, the only significant difference being "0.63" embossed on one vial and "1.25" embossed on the other. Both packages are already difficult to read, being clear plastic with raised lettering. The potential exists to give 50% or 200% of the prescribed dose.

Sepracor letter to the reporter dated 7/18/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible and would further differentiate the Xopenex Inhalation Solution.

MEDERR DDP REPORT

Access Number: 053888
28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 29-Mar-0 **Date of Report** 29-Mar-0

Product Name:	Xopenex	**Container Type:**	Vial
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Roxane	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053888

28-Oct-02 02:52:03 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Xopenex (Levalbuterol) SVN (small volume nebulizer) package is very hard to read. The label is on clear plastic wit raised lettering for drug name and strength. This product comes in two strengths. The packaging is identical to Roxane's product Ipratropium SVN (clear plastic with raised lettering). This is a set up for a medication error.

Sepracor letter to the reporter dated 7/18/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.6 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the d strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 053893
28-Oct-02 02:52:03 PM **erf**

Date Received at USP: 30-Mar-0 **Date of Report** 30-Mar-0

Product Name:	Pulmicort Respules	**Container Type:**	
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra	**NDC Number:**	00186-1988-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.25 mg/2 mL	**Sample Available:**	No

Product Name:	Pulmicort Respules	**Container Type:**	
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra	**NDC Number:**	00186-1989-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.5 mg/2 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053893

28-Oct-02 02:52:04 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

The medications require different packaging and/or labeling. Printing the name and strength of the medication in color would be most useful. A consideration to prevent potential errors in the future is to remove the medication from the hospital formulary.

REMARKS

Problem:

Pulmicort Respules are manufactured in two strengths. The two product strengths are virtually identical in appearance, the only significant difference being "0.25" embossed on one vial and "0.5" embossed on the other. Both packages are already difficult to read, being clear plastic with small raised lettering. The potential exists to give 50% or 200% of the prescribed dose.

MEDERR DDP REPORT

Access Number: 053970
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 17-Apr-01 **Date of Report** 17-Apr-01

Product Name:	Xopenex	**Container Type:**	Ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-96
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Roxane	**NDC Number:**	00054-8404-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/2.5 mL	**Sample Available:**	No

Was the medication administered to or used by patient? Yes

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Respiratory therapist

Describe Outcome: No adverse outcome reported.

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Respiratory therapist?

When and how was the error discovered? Unknown

Where did the error occur? Hospital

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053970

28-Oct-02 02:52:04 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

The packaging of Xopenex and Ipratropium Bromide are very similar. The manufacturer should add color ink or a label to one or both of these products. The facility has made the following changes in order to prevent this error from occurring in the future: 1) Two "info-grams" sent to all pharmacy locations via the order entry computer system to notify the pharmacy staff of the similar appearance of these products (Xopenex and Ipratropium). 2) The hospital has ordered a new brand of Ipratropium (Dey). 3) Central pharmacy will dispense all Xopenex in a zip lock bag with a label indicating that it contains Albuterol.

REMARKS

Problem:

Xopenex was administered to the patient by the respiratory therapist instead of Ipratropium. No harm reported. The containers are very similar. Both are in clear plastic ampuls for nebulization. It is difficult to read the writing on the ampuls because it is the same color as the plastic ampul.

Sepracor letter to the reporter dated 7/19/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 053971
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 17-Apr-01 **Date of Report** 17-Apr-01

Product Name: Xopenex	**Container Type:** Ampul
Generic Name(s): Levalbuterol Hydrochloride	**Container Size:**
Manufacturer: Sepracor Inc.	**NDC Number:** 63402-0513-96
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 1.25 mg/3 mL	**Sample Available:** No

Product Name: Ipratropium Bromide	**Container Type:** Ampul
Generic Name(s): Ipratropium Bromide	**Container Size:**
Manufacturer: Roxane	**NDC Number:** 00054-8404-11
Labeler:	**Adm. Route:** Inhalation
Dosage Form: Solution	**Lot Number(s):**
Strength: 0.5 mg/2.5 mL	**Sample Available:** No

Was the medication administered to or used by patient? No

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Technician, pharmacy

Describe Outcome:

If the medication did not reach the patient, describe the intervention. The error was discovered by the pharmacist during check of medic carts.

Who discovered the error? Pharmacist

When and how was the error discovered?

Where did the error occur? Hospital pharmacy

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 053971

28-Oct-02 02:52:04 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Xopenex and Ipratropium Bromide both have similar packaging. The manufacturer should add colored ink or to one or both of these products. The facility has made the following changes in order prevent this error from in the future: 1) Two "info-grams" sent to all pharmacy locations via the order entry computer system to notif pharmacy staff of the similar appearance of these products (Xopenex and Ipratropium). 2) The hospital has or new brand of Ipratropium (Dey). 3) Central pharmacy will dispense all Xopenex in a zip lock bag with a labe indicating that it contains Albuterol.

REMARKS

Problem:

Xopenex was dispensed in the medication cart instead of Ipratropium. The medications were initially placed i cart by the pharmacy technician. The pharmacist checking the carts noted that there were two ampuls of each medication in the cart. The containers are extremely similar. Both are clear plastic ampuls for nebulization. I difficult to read the writing on the ampuls because it is the same color as the plastic ampul.

Sepracor letter to the reporter dated 7/19/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalati Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separ locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In or increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printin strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 053972
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 17-Apr-01 **Date of Report** 17-Apr-01

Product Name:	Xopenex	**Container Type:**	Ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-96
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Roxane	**NDC Number:**	00054-8404-11
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/2.5 mL	**Sample Available:**	No

Product Name:	Pulmozyme	**Container Type:**	Ampul
Generic Name(s):	Dornase Alfa	**Container Size:**	
Manufacturer:	Genentech	**NDC Number:**	50242-0100-39
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	2.5 mg/2.5 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 053972

28-Oct-02 02:52:04 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

The manufacturer should add colored ink or a label to the products. The facility has made the following changes in order to prevent an error from occurring: 1) Two "info-grams" sent to all pharmacy locations via the order entry computer pharmacy staff of the similar appearance of these products (Xopenex, Ipratropium, and Pulmozyme). 2) The hospital has ordered a new brand of Ipratropium (Dey). 3) Central pharmacy will dispense all Xopenex in a zip lock bag with a label indicating that it contains Albuterol.

REMARKS

Problem:

The packaging for Dornase Alfa (Pulmozyme) 2.5 mg/2.5 mL container by Genetech (NDC (National Drug Code) 50242-0100-39) is very similar to Xopenex and Ipratropium. All are in clear plastic ampuls for nebulization. It is difficult to read the writing on the ampuls because it is the same color as the plastic ampul.

Genentech, Inc. letter to USP dated 5/29/01: The company has completed the investigation of the report. Pulmozyme is an enzyme indicated for the treatment of patients with cystic fibrosis which was approved by the FDA in December 1993. During the approval process, the FDA reviewed the packaging and ampule configuration for Pulmozyme and found it to be acceptable. The ampules are labeled with the product name, lot number, expiration date, and strength. In addition, the secondary packaging for Pulmozyme is clearly labeled with the appropriate information for proper identification. The report was conveyed to the Regulatory Affairs department, and it was concluded that no action is necessary. Both the packaging and the ampules for Pulmozyme are well labeled with the name and strength which should be verified before administration.

Sepracor letter to the reporter dated 7/19/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 054161
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 13-Jun-01 **Date of Report** 13-Jun-01

Product Name:	Xopenex	**Container Type:**	
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Product Name:	Atrovent	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Roxane	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 054161

28-Oct-02 02:52:04 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Levalbuterol (Xopenex) medication nebulizers look almost exactly like the Ipratropium medication nebulizers from Roxane. There is a serious potential for error.

Sepracor letter to the reporter dated 7/18/01. The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and the red for the 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible.

MEDERR DDP REPORT

Access Number: 054263
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 06-Aug-0 **Date of Report** 03-Aug-0

Product Name:	Albuterol Sulfate	**Container Type:**	
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0831-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	2.5 mg/3 mL	**Sample Available:**	No
Product Name:	Ipratropium Bromide	**Container Type:**	Vial
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0751-23
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/2.5 mL	**Sample Available:**	No
Product Name:	Xopenex	**Container Type:**	
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-2513-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

MEDERR DDP REPORT

Access Number: 054263

28-Oct-02 02:52:04 PM **erf**

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Add some sort of coloring to the vials or use an actual label on the vials instead of the raised lettering.

REMARKS

Problem:

Alpharma's Albuterol Sulfate and Ipratropium, and Sepracor's Xopenex are packaged in identical plastic vials with raised letters. Only the product name is different. The Alpharma products have an "A" or an "I" on the appropriate tab on the vials, but it is only on one side of the tab.

Sepracor letter to the reporter dated 9/20/01: The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil puch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and red for the 1.25 mg/3 mL). The LPDE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluationg the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this, require FDA (Food and Drug Administration) approval before being marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 054293
28-Oct-02 02:52:04 PM **erf**

Date Received at USP: 13-Aug-0 **Date of Report** 13-Aug-0

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Zenith Goldline	**NDC Number:**	00172-6405-44
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0751-23
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054293

28-Oct-02 02:52:05 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The packaging and labeling for Ipratropium Bromide and Albuterol Sulfate inhalation solutions are practically identical and hard to read. The drug names and dosing information are extremely hard to read due to the almost transparent font. There is a high potential of confusion among these two products.

MEDERR DDP REPORT

Access Number: 054341

28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 29-Aug-0 **Date of Report** 23-Aug-0

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0751-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/2.5 mL	**Sample Available:**	No

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0831-30
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	2.5 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054341

28-Oct-02 02:52:05 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Attach a label to the container or add some color. The pharmacy is considering purchasing a different product at an additional cost because of the packaging concern.

REMARKS

Problem:

The packaging of Ipratropium Bromide 0.02% and Albuterol 0.083% is similar. Also, both are in clear containers with raised lettering making it difficult to read the name of the drug.

MEDERR DDP REPORT

Access Number: 054342

28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 29-Aug-0 **Date of Report** 23-Aug-0

Product Name:	DuoNeb	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide Albuterol Sulfate	**Container Size:**	
Manufacturer:	Dey	**NDC Number:**	49502-0672-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.5 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

Attach a label to the container and add some color.

REMARKS

Problem:

The raised lettering on the clear plastic container of DuoNeb makes it difficult to read the name of the product and the ingredients. If you do not look closely, you might not notice that DuoNeb contains Ipratropium Bromide and Albuterol Sulfate.

MEDERR DDP REPORT

Access Number: 054336
28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 24-Aug-0 **Date of Report** 24-Aug-0

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0751-23
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054336

28-Oct-02 02:52:05 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Not allowing clear vials with clear writing.

REMARKS

Problem:

This potential error was reported by the respiratory staff. The hospital recently switched companies that supply respiratory products due to a contract change. The Ipratropium Bromide inhalation solution 0.02% 2.5 mL unit-dose vials distributed by Alpharma (00472-0751-23) look identical to Xopenex inhalation solution unit-dose vials (63402-0513-34). Both vials are opaque with non-colored, raised lettering. They are very hard to read even when there was not a similar product. The respiratory staff is afraid that one will be accidentally substituted for the other one.

Sepracor letter to the reporter dated 9/20/01: The current packaging for Xopenex (Levalbuterol HCL) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil puch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for the 0.63 mg/3 mL and red for the 1.25 mg/3 mL). The LPDE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the product, Sepracor is currently evaluationg the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this, require FDA (Food and Drug Administration) approval before being marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 054380

28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 07-Sep-01 **Date of Report** 07-Sep-01

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	3 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0831-23
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No
Product Name:	Cromolyn Sodium	**Container Type:**	Plastic ampul
Generic Name(s):	Cromolyn Sodium	**Container Size:**	2 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0750-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	10 mg/mL	**Sample Available:**	No
Product Name:	Pulmozyme	**Container Type:**	Plastic ampul
Generic Name(s):	Dornase Alfa	**Container Size:**	N/I
Manufacturer:	Genentech	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	N/I	**Sample Available:**	No
Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	N/I
Manufacturer:	Astra Zeneca	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	N/I	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

MEDERR DDP REPORT

Access Number: 054380

28-Oct-02 02:52:05 PM **erf**

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided?

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

There is a potential for errors regarding the respiratory care unit-dose medications Albuterol and Cromolyn (manufactured by Alpharma), Pulmicort respules (manufactured by Astra), and Pulmozyme (manufactured by Genentech). These products are packaged in clear plastic single-use ampuls whose labeling on each ampul is terrible. The letters are raised on the plastic container, but not a different color. The letters are the same material as the plastic container. The reporter has had many respiratory care therapists complain of this; they are concerned that a wrong dose or wrong medication will be administered to the patient.

MEDERR DDP REPORT

Access Number: 054425
28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 28-Sep-01 **Date of Report** 28-Sep-01

Product Name:	DuoNeb	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate Ipratropium Bromide	**Container Size:**	3 mL
Manufacturer:	Novartis	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	3 mg/0.5 mg	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The pharmacies at the facility have reported that the packaging for the inhalation product DuoNeb is difficult to read and there exists the risk of error in using this drug. DuoNeb consists of a 3 mL inhalant solution (Ipratropium and Albuterol) packaged in a clear plastic vial, with several vials in a foil pouch. The pouch is clearly labeled DuoNeb with the ingredients, lot number, expiration date, and other information. The problem is when the clear vials are removed from the packaging. The vials are clear plastic containing a clear solution. The lettering on the vials is not printed, but

raised in clear plastic. This makes it difficult to clearly see the name of the drug, ingredients, lot number, and expiration date. While the foil pouch is clearly marked, the facility has noted the practice of opening the pouch, taking the vials out and then discarding the pouch. The result is loose vials that are not clearly marked. In addition, the labeling on the foil package shows the Albuterol Sulfate content to be 3.0 mg. The small print makes the strength appear to be 30 mg. The practice of adding trailing zeros to the strength of drugs is commonly implicated in medication errors. The facility feels that this type of packaging and labeling may lead to medication errors if the wrong vial is picked up.

MEDERR DDP REPORT

Access Number: 054577
28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 26-Oct-01 **Date of Report** 26-Oct-01

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra Zeneca	**NDC Number:**	00186-1988-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.25 mg/2 mL	**Sample Available:**	No

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	2 mL
Manufacturer:	Astra Zeneca	**NDC Number:**	00186-1989-04
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.5 mg/2 mL	**Sample Available:**	No

Was the medication administered to or used by patient? No

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Pharmacist

Describe Outcome:

If the medication did not reach the patient, describe the intervention. The error was caught at patient counseling.

Who discovered the error? Pharmacist

When and how was the error discovered? The error was discovered while discussing the medication strength with the patient.

Where did the error occur? Pharmacy, community

Was another practitioner involved in the error? No

If yes, what type of practitioner?

Was patient counseling provided? Yes

If yes, before or after error was discovered? Both

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054577

28-Oct-02 02:52:05 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Take time to check prescriptions and institute the use of a bar scanner.

REMARKS

Problem:

The pharmacy had regular staffing and the pharmacist chose the wrong strength and quantity needed to fill the prescription. The prescription called for Pulmicort Respules 0.5 mg/2 mL with a quantity of 120 mL. The prescription was filled instead as Pulmicort 0.25 mg/2 mL with a quantity of 60 mL.

MEDERR DDP REPORT

Access Number: 054588
28-Oct-02 02:52:05 PM **erf**

Date Received at USP: 31-Oct-01 **Date of Report** 31-Oct-01

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0512-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.63 mg/3 mL	**Sample Available:**	No

Product Name:	Xopenex	**Container Type:**	Plastic ampul
Generic Name(s):	Levalbuterol Hydrochloride	**Container Size:**	3 mL
Manufacturer:	Sepracor Inc.	**NDC Number:**	63402-0513-24
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	1.25 mg/3 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054588

28-Oct-02 02:52:06 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The reporter may have not had an incident, but they see a potential for errors with the product Xopenex (Levalbuterol HCL (Hydrochloride)) by Sepracor. Sepracor produces two strengths of the medication, 0.63 mg/3 mL and 1.25 mg/3 mL, in unit-dose packages. The unit-dose packages look the same. The difference in dose is stamped on the vial, but it is the same color as the rest of the package. You have to look very hard in good light to note the difference.

Sepracor letter to the reporter dated 06-Dec-01: The current packaging for Xopenex (Levalbuterol Hydrochloride) Inhalation Solution consists of the low-density polyethylene (LDPE) unit-dose vial, an outer foil pouch, and a packaging carton. The cartons and foil pouches both differentiate the strengths using label text and colored markings (yellow for 0.63 mg/3 mL and red for 1.25 mg/3 mL). The LDPE unit-dose vials list the product strength in three separate locations on each unit-dose vial and again on the bottom flashing used to connect the 12 unit-dose vials. In order to increase the visible differentiation of the two strengths, Sepracor is currently evaluating the feasibility of ink printing the dose strength onto the top flashing portion of each vial. This could make the information more readily visible. Please be aware that many product changes, including labeling changes such as this, require FDA (Food and Drug Administration) approval before being marketed to consumers and therefore require additional time to implement.

MEDERR DDP REPORT

Access Number: 054601
28-Oct-02 02:52:06 PM **erf**

Date Received at USP: 06-Nov-0 **Date of Report** 06-Nov-0

Product Name:	Cromolyn Sodium	**Container Type:**	Plastic ampul
Generic Name(s):	Cromolyn Sodium	**Container Size:**	2 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0752-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	20 mg/2 mL	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	Plastic ampul
Generic Name(s):	Ipratropium Bromide	**Container Size:**	2.5 mL
Manufacturer:	Alpharma USPD, Inc.	**NDC Number:**	00472-0751-60
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient? Yes

Date of Event: [redacted]

What type of staff or health care practitioner made the initial error? Intern, pharmacy

Describe Outcome: The patient benefited and became better with the medication.

If the medication did not reach the patient, describe the intervention.

Who discovered the error? Physician

When and how was the error discovered? The error was discovered when the physician called the patient's parents the day after the office visit for a follow-up.

Where did the error occur? Pharmacy, community

Was another practitioner involved in the error? Yes

If yes, what type of practitioner? Pharmacist

Was patient counseling provided? Yes

If yes, before or after error was discovered? After

Number of occurrences:

Patient information that might be relevant:
The patient is a 2-year-old Caucasian female.

MEDERR DDP REPORT

Access Number: 054601

28-Oct-02 02:52:06 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

Decrease distractions to allow the verifying pharmacist to check the medication being dispensed more carefully.

REMARKS

Problem:

A physician called in a prescription to the pharmacy and the intern tried to take it over the phone, but did not understand the physician. The pharmacist took over and received the prescription. The intern was confused. The prescription was typed into the computer as Ipratropium (Atrovent) instead of Cromolyn (Intal). The prescription was filled, but not properly checked before dispensing it to the patient's parent. Both Ipratropium Bromide and Cromolyn Sodium solution boxes look similar. Thus, it is hypothesized that the medication was picked before the prescription was typed in and then typed in based on the wrong medication selected.

MEDERR DDP REPORT

Access Number: 054698

28-Oct-02 02:52:06 PM **erf**

Date Received at USP: 26-Dec-01 **Date of Report** 26-Dec-01

Product Name:	DuoNeb	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate Ipratropium Bromide	**Container Size:**	3 mL
Manufacturer:	Dey	**NDC Number:**	49502-0672-30
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

Several of the respiratory medications available have similar, if not duplicative, packaging. With the addition of DuoNeb to this group, the facility has yet another item to add into the category. The reporter understands that the FDA (Food and Drug Administration) has a lot to do with this by disallowing inks directly on the packaging and other stability requirements. The facility currently does not add any ancillary labeling to this product because more steps in the process add more opportunities for error. Fortunately for the facility, the therapists, who can be alerted with relative

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ease, give most of these respiratory products that are dispensed from pharmacy.

Dey letter to USP dated 21-Jan-02: It is very important that health care professionals carefully read the labeling of the drug product prior to dispensing to a customer. The labeling for DuoNeb was developed in consultation with the Food and Drug Administration (FDA). The labeling was approved by the FDA and may not be altered without prior approval from the FDA. The company does not anticipate a change in the labeling for DuoNeb in the foreseeable future.

MEDERR DDP REPORT

Access Number: 054744

28-Oct-02 02:52:06 PM **erf**

Date Received at USP: 28-Jan-02 **Date of Report** 28-Jan-02

Product Name:	Albuterol Sulfate	**Container Type:**	Plastic ampul
Generic Name(s):	Albuterol Sulfate	**Container Size:**	
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	00487-9501-25
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.083%	**Sample Available:**	No

Product Name:	Ipratropium Bromide	**Container Type:**	
Generic Name(s):	Ipratropium Bromide	**Container Size:**	
Manufacturer:	Nephron Pharmaceutical Corporation	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:	0.02%	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054744

28-Oct-02 02:52:06 PM **erf**

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The facility is concerned about the new packaging for the unit-dose inhalation solutions. The specific brand the facility is now stocking is Nephron Pharmaceuticals Corporation. The Albuterol Sulfate 0.083% solution and the Ipratropium Bromide 0.02% solution both come in clear, unit-dose vials. The vials are the same shape, with the Ipratropium Bromide a little taller. The Ipratropium Bromide has an embossed "I" on the top, and the Albuterol Sulfate an embossed "A." This was discovered by respiratory therapists looking at the vials.

MEDERR DDP REPORT

Access Number: 054754

28-Oct-02 02:52:06 PM **erf**

Date Received at USP: 13-Feb-02 **Date of Report** 13-Feb-02

Product Name:	Heparin Sodium	**Container Type:**	Plastic ampul
Generic Name(s):	Heparin Sodium	**Container Size:**	
Manufacturer:	Automatic Liquid Packaging	**NDC Number:**	
Labeler:	American Pharmaceutical Partners	**Adm. Route:**	Injection
Dosage Form:	Injectable	**Lot Number(s):**	
Strength:	10 units/mL	**Sample Available:**	No
Product Name:	Plastic Ampul for Respiratory Medications	**Container Type:**	Plastic ampul
Generic Name(s):	Plastic Ampul for Respiratory Medications	**Container Size:**	
Manufacturer:	Various	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Solution	**Lot Number(s):**	
Strength:		**Sample Available:**	No
Product Name:	SmartAmp	**Container Type:**	Plastic ampul
Generic Name(s):	SmartAmp	**Container Size:**	
Manufacturer:	Avitro	**NDC Number:**	
Labeler:		**Adm. Route:**	Injection
Dosage Form:	Injectable	**Lot Number(s):**	
Strength:		**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

MEDERR DDP REPORT

Access Number: 054754

28-Oct-02 02:52:06 PM **erf**

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The SmartAmp looks exactly like a respiratory therapy "pillow," however is being used as an injectable. There are three areas that the reporter has concerns: (1) look-alike of injectable to respiratory medication, (2) labeling insufficiencies, and (3) injectable not having a rubber stopper (open to air container used for direct IV (intravenous) injection).

Information per call to reporter on 06-Feb-02: The product involved is Heparin Sodium preservative free 10 units/mL. Although Heparin Sodium is a drug shortage product, a drug representative from Avitro informed the reporter that Heparin Sodium is available in the SmartAmp. The reporter is not identifying any specific respiratory product, but notes that the SmartAmp resembles the respiratory unit-dose packaging.

MEDERR DDP REPORT

Access Number: 054911

28-Oct-02 02:52:06 PM **erf**

Date Received at USP: 19-Apr-02 **Date of Report** 19-Apr-02

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	
Manufacturer:	Astra Zeneca	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.25 mg/2 mL	**Sample Available:**	No

Product Name:	Pulmicort Respules	**Container Type:**	Plastic ampul
Generic Name(s):	Budesonide	**Container Size:**	
Manufacturer:	Astra Zeneca	**NDC Number:**	
Labeler:		**Adm. Route:**	Inhalation
Dosage Form:	Suspension	**Lot Number(s):**	
Strength:	0.5 mg/2 mL	**Sample Available:**	No

Was the medication administered to or used by patient?

Date of Event:

What type of staff or health care practitioner made the initial error? N/A

Describe Outcome:

If the medication did not reach the patient, describe the intervention.

Who discovered the error? N/A

When and how was the error discovered?

Where did the error occur? N/A

Was another practitioner involved in the error?

If yes, what type of practitioner?

Was patient counseling provided? No

If yes, before or after error was discovered?

Number of occurrences:

Patient information that might be relevant:

MEDERR DDP REPORT

Access Number: 054911

28-Oct-02 02:52:06 PM **erf**

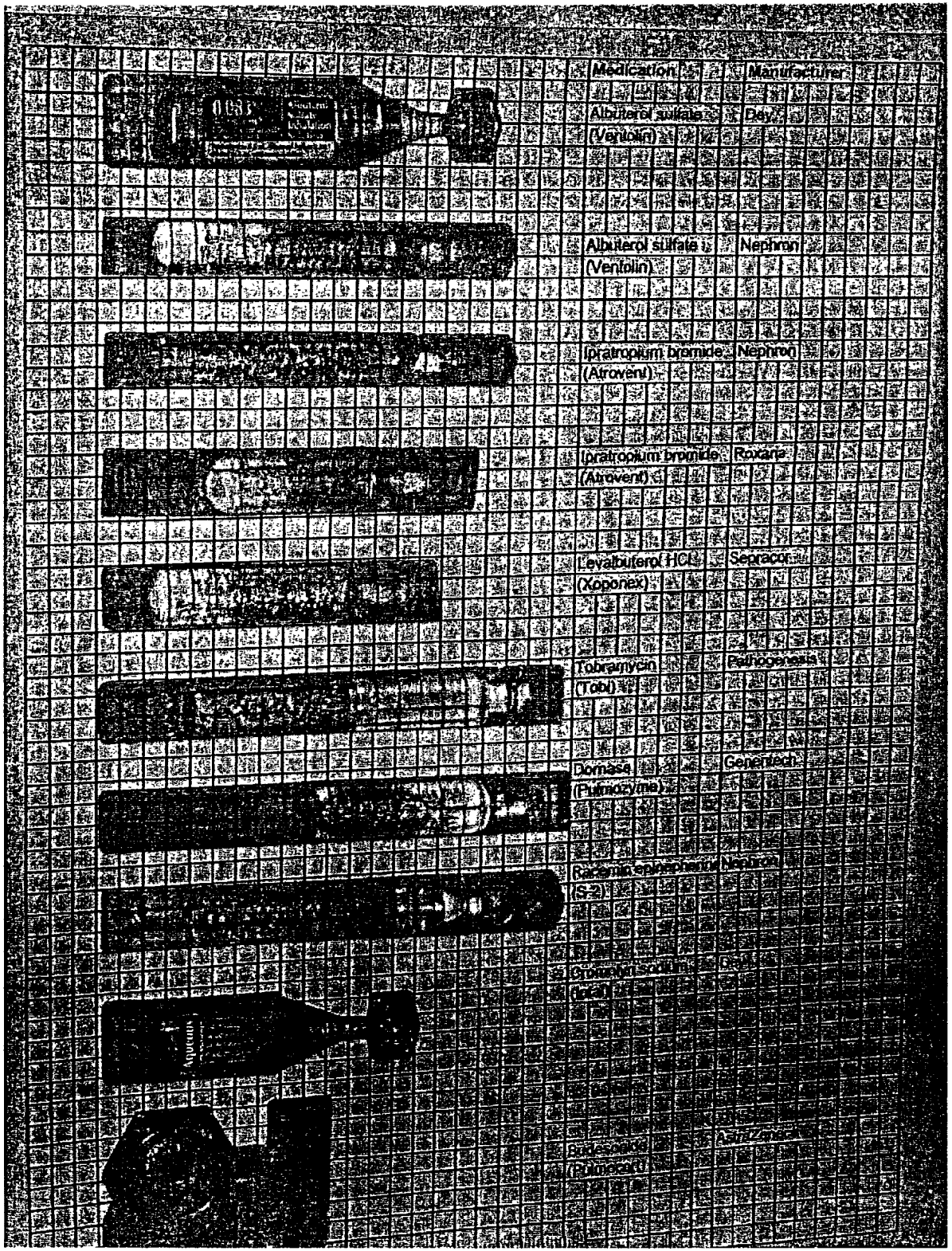
Reporter's recommendations or policies to prevent future similar errors:

REMARKS

Problem:

The respiratory staff asked the facility to initiate a medication alert for some inhalation products. The unit-dose packaging for the two strengths of Pulmicort Respules (0.25 mg/2 mL and 0.5 mg/2 mL) is very similar. Both are made of clear plastic and have raised lettering. Neither have any coloration for easy identification. The facility's respiratory therapists often carry individual unit-dose containers in their pockets without the outside packaging

Information per email from reporter: Albuterol unit-dose, manufactured by Dey, has colored packaging that makes it easy to identify.


Medication
Manufacturer
Albuterol sulfate
(Ventolin)
Dey
Albuterol sulfate
(Ventolin)
Nephron
Ipratropium bromide
(Atrovent)
Nephron
Ipratropium bromide
(Atrovent)
Roxane
Levalbuterol HCL
(Xoponex)
Sepracor
Tobramycin
(Tobi)
Pathogenesis
Dornase
(Pulmozyme)
Genentech
Racemic epinephrine
(S-2)
Nephron

Aqueous